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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/729,551      | 12/05/2003  | Stephen D. Pacetti   | 50623.355           | 4350             |

7590 01/11/2006

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EXAMINER

FULLER, ERIC B

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1762

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                            |  |
|------------------------------|--------------------------------------|--------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/729,551 | <b>Applicant(s)</b><br>PACETTI, STEPHEN D. |  |
|                              | <b>Examiner</b><br>Eric B. Fuller    | <b>Art Unit</b><br>1762                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 17, 2005 has been entered.

### ***Response to Arguments***

Applicant argues that one of ordinary skill in the art would interpret "smoother" in claim 1 to mean that the coating resulting from the adjusted pressure process would be smoother than the coating resulting from the process in which the pressure is ambient. This is the same interpretation that the examiner was best able to deduce in the previous Office Action. In view of the specification, the applicant's arguments have been found convincing. The 35 U.S.C. 112 rejections of the previous Office Action have been withdrawn, accordingly.

Applicant argues against the art rejections and alleges that the '370 patent teaches that the reduced pressure process produces a coating that has less smoothness. This is not found convincing. The examiner finds no teaching in the reference of this. Instead, it is taught that the reduced pressure evaporates the solvent

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around the discrete particles that eventually comprises the coatings. As some solvent is evaporated, the size of each discrete particle is reduced. Smaller particle sizes results in less void space between the particles and inherently results in a smoother coating. Therefore, the reference reads on the reduced pressure resulting in smoother coatings than ambient pressure would result in. This is sufficient to read on the applicant's claims. Accordingly, the art rejections of the previous Office Action have been maintained.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 8-11, 13-15, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Panagiotou et al. (US 6,143,370).

Panagiotou discloses a process comprising inserting an implantable medical device into a chamber, adjusting the pressure of the chamber to less than ambient pressure to control a rate of solvent evaporation and spraying a coating composition comprising a polymer in a solvent optionally containing a drug (therapeutic agent) onto the medical device while the medical device is rotated, the pressure controlling the rate of evaporation of the solvent (abstract, col. 1, lines 45-50, col. 2, lines 29-50, col. 4, lines 23-36, col. 5, lines 48-53 and example 1). The pressure is clearly chosen based on the solvent used to insure the proper evaporation rate. Solvents of the dependent claims are disclosed at the sections cited above.

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As to the newly added limitations, it is explicitly taught that the pressure is lowered in order to evaporate some of the solvent before the droplets hits the substrate (abstract). This inherently would result in a smoother coating than would result if no or less evaporation existed, as would be the case at ambient pressures. This reads on the applicant's limitation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 7, 12, 16, and 21-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panagiotou et al. (US 6,143,370) in view of Ding et al. (US 5,837,313).

Panagiotou is silent as to the type of therapeutic agent and therefore does not explicitly disclose those of claims 3, 12, 21 and 31. However, because Ding discloses at (col. 4, lines 65-68) that the claimed drugs are suitable to apply in stent coatings, it would have been obvious to apply these therapeutics given their ad-recognized suitability for use in stent coatings. As to claims 19 and 20, use of the claimed antibiotic would have been obvious for the reasons established at page 6 of the last office action. As to claims requiring linear movement of the stent during coating, this would have been obvious in view of the teachings in Ding described at page 7 of the first office action.

### ***Conclusion***

This is an RCE of applicant's earlier application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric B. Fuller whose telephone number is (571) 272-1420. The examiner can normally be reached on Mondays through Thursdays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks, can be reached on (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EBF



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**SUPERVISORY PATENT EXAMINER**